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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,639	10/17/2001	Michael J.P. Lawman	MOR-100D2	8705

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

981,639

Applicant(s)

LAWMAN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 2/17/05
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 14-21, 23-28, 30-32, 34-37, 39-46, 48-58 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 14-20, 23, 26-28, 30-31, 34, 37, 39-45 is/are allowed.
- ☒ Claim(s) 21, 24-25, 32, 35-36, 46, 48-58 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/05 has been entered.

Following entry of the amendment of 2/17/05 claims 14-21, 23-28, 30-32, 34-37, 39-46, 48-58 is pending and renders examination.

Applicant's amendment of 2/17/05 has overcome 112, first paragraph, rejections of record, as would have the after final amendment received 11/12/04. See page 2 of advisory action of 1/11/05 for a listing of rejections that have been overcome.

It is to be noted that the listing of 112 rejections that have been overcome should also have included the following:

The rejection of claims 23 and 24 for reciting the term "sequentially oriented"; applicant's insertions of "layer" in claim 14 and "layers" in claim 23 have overcome.

Applicant's urgings filed on 2/17/05 have overcome the following previously stated bases of rejection:

The 112, first paragraph rejection of claims 37 and 48, as well as dependent claims, 38, 40, 43-44, 46-47, 49-51, 55-56 and 58-59 for containing new matter (see FINAL rejection of (8/12/04); the examiner concurs that disclosure of a required intermediate provides a basis for claiming the intermediate.

The 101/112, first paragraph rejection of claims 24-25 and 35-36 pertaining to utility/use; examiner concurs that those in the art would readily recognize how to use the disclosed multilayered immunomatrix devices in a manner to conduct both positive and negative selections, given the fact that the teachings throughout relate both positive and negative selection methods.

The following 112 rejections of record (FINAL rejection of 8/12/04) have been maintained.

Claims 21, 32, 46 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

Claims 21, 32, 46 and 58 recite new matter by reciting that "said Fc receptor specifically binds to the Fc portion of Ig G antibody." Applicant has urged that page 10 lines 17-18 support by virtue of disclosing Protein -G, which is a receptor for the Fc of IgG. The examiner notes that Protein -G is but one species of the subgenus of members that specifically bind the Fc of IgG. For example, FcRI is also such a receptor. Since the not originally disclosed subgenus encompasses more than the one specified member that is Protein -G, the claims are broader than the originally disclosed invention.

Claims 24-25 and 35-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

As previously noted (FINAL rejection of 8/12/04 at page 5) the claims have been rejected because there is no description of a single matrix, of two or more immunopolymer layers, that has one immunopolymer binding to an antigen not expressed on a rare cell and another immunopolymer binding to an antigen that is expressed on a rare cell. The examiner found no such language in the para. spanning pages 11-12 and found therein only teachings of positive selection in all layers.

Applicant has presently urged that examples 4-5 support. However, the examiner finds no support in example 4; the polypyrrole membranes disclosed therein are disclosed as being prepared separately; those having anti-CD34 or anti-CD19 appear to have been placed in separate wells (page 17, last para.); therein there is no disclosure of any matrix device that contained both of the anti-CD 34 and anti – CD 19 antibodies, to which cells were added such that there would be a positive selection occurring within one layer and a negative selection within the other layer.

In like manner, in Example 5, the examiner finds a disclosure of only a single type of immunopolymer membrane - - i.e. one that has anti-CD 34. There is no disclosure of any matrix of two layers, having a different antibody in each of the layers.

Applicant's urgings filed on 2/17/05 have been considered but are unconvincing for the reasons stated above with respect to claims 21, 24-25, 32, 35-36, 46 and 58.

Regarding the issue of whether there can be a "net negative charge", as recited in claims 30 and 40; with the base claims requiring a polyphenol polymer (see advisory action of 1/11/05, at page 3), the examiner concurs that there can be a net negative charge, due to the introduction of "negatively charged, pH-type titrateable groups into the membrane", as disclosed at page 8, lines 14-15.

Applicant's amendment of 2/17/05 has necessitated the following new grounds of rejection:

Claims 48-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter because base claim 48 recites "cell free" which is deemed to be a defacto negative limitation.

Applicant appears to have introduced the term "cell free" instead of "non-cell bound" (as recited in the non-entered amendment of 11/12/04) in order to avoid explicit negative language. While no negative language per se has been entered, the result is the same whether one recites "non-cell bound" or "cell-free". In each case the entry of the recitation excludes the same non –originally described subgenus of the genus of molecules.

Applicant's urgings that everything exemplified and discussed in the original disclosure was a "free molecule" is unconvincing because the originally filed language was open in scope and would have included multimeric complexes of such free

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molecules, constructs (e.g. such as liposomes) bearing such molecules, or whole cells bearing such molecules. Applicant did not exclude any of these in this description.

Because of the introduction of the limitation "cell-free" in claim 48, the prior art rejection over Wallace et al has been withdrawn; however claim 48 and its dependents contain new matter (above para.) Should any change in the claims introduced to overcome the new matter rejection place the claims within the scope of the teaching of Wallace et al, this prior art will be cited again in a FINAL rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Saunders/LR  
May 6, 2005

*David A. Saunders*

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PRIMARY EXAMINER  
ART UNIT 182